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The effect of local anaesthetic on pain following oral surgery under general anaesthetic

Submission date 11/12/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/01/2009	**Overall study status** Completed	
Last Edited 10/05/2016	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-000254-13

Protocol serial number
RD/613/07

Study information

Scientific Title
A double blind randomised placebo controlled study assessing the effect of intra-operative local anaesthetic administration on post-operative pain in adolescent children undergoing oral surgery under general anaesthetic to facilitate orthodontic treatment

Study objectives
Intra-operative administration of local anaesthetic significantly reduces post-operative pain experience in children aged 12 to 16 years having ambulatory oral surgery to facilitate orthodontic treatment under general anaesthetic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales REC Panel B, 14/10/2008, ref: 08/WSE02/57

Primary study design
Interventional

Study design
Double-blind randomised placebo-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain following ambulatory oral surgery

Interventions
Treatment group: standard dental local anaesthetic in the form 2% lidocaine hydrochloride with 1 in 80000 adrenaline by local injection
Control group: saline by local injection

Treatment takes place on a single day. No follow-up.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lidocaine hydrochloride

Primary outcome(s)
Post-surgical pain using a Visual Analogue Scale, measured pre-surgery, at 30 minutes, 1 hour and 2 hours post-surgery.

Key secondary outcome(s)
Measurement of time to rescue analgesia.

Completion date
20/02/2010

Eligibility

Key inclusion criteria
1. Aged 12 to 16 years, either sex
2. Requiring surgery necessitating the raising of a mucoperiosteal flap and bone removal in at least one but not more than two sites
3. Suitable for ambulatory surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
16 Years

Sex
All

Key exclusion criteria
1. Age under 12 years
2. History of allergy to local anaesthetic of the amide type or to any components of the injectable formulation, paracetamol or non-steroidal anti-inflammatory drugs

Exclusion criteria due to the presence of adrenaline in the local anaesthetic formula:
3. Arterial hypertension
4. Coronary disease
5. Valvular heart disease

Standard anaesthetic-based exclusions for ambulatory surgery:
6. American Society of Anaesthesiologists (ASA) grade greater than 2
7. Body mass index greater than 35
8. Poorly controlled asthma

Date of first enrolment
20/02/2009

Date of final enrolment
20/02/2010

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Royal Gwent Hospital
Newport
United Kingdom
NP20 2UB

Sponsor information

Organisation
Gwent Healthcare NHS Trust (UK)

ROR
https://ror.org/045gxp391

Funder(s)

Funder type
Government

Funder Name
Gwent Healthcare NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No